

REMARKS

Claims 1, 3-14 and 16-22 were pending in this application prior to issuance of the Office Action dated May 21, 2009. According to the foregoing amendments, claims 1, 3, 17, 18, 19, 20 and 22 have been amended, claims 12 and 14 have been cancelled without prejudice and new claim 23 has been added. Accordingly, after entry of the foregoing amendments, claims 1, 3-11, 13 and 16-23 are pending in the instant application.

Support for the claim amendments and new claim 23 presented herein can be found throughout the specification and in the claims as originally filed. Specifically, support for amended claim 17 can be found at least at paragraph [0008] of the published application. Support for new claim 23 can be found at paragraphs [0028] and [0036] of the published application. No new matter has been introduced by the foregoing amendments or new claim.

The foregoing amendments to the claims and cancellation of certain claims have been made *solely* in the interest of expediting prosecution and allowance of the application. These amendments are not related to issues of patentability. Applicants reserve the right to pursue the claims as originally filed or previously pending in this or separate application(s).

Rejoinder of Withdrawn Claims

Claims 13, 16 and 18-22 have been withdrawn from consideration as being directed to non-elected inventions. It is Applicants' understanding that method claims that depend from or include all the limitations of elected composition claims are subject to rejoinder upon allowance of the composition claims. Accordingly, Applicants respectfully request rejoinder of claims 13, 16 and 18-22 upon allowance of the composition claims, pursuant to MPEP 821.04. Additionally, in the interest of expediting prosecution, Applicants respectfully request consideration and examination of these withdrawn method claims concurrently with that of the elected composition claims currently under examination.

Drawings

As requested in the Office Action, Applicants hereby submit new formal drawings in compliance with 37 CFR 1.121(d). Applicants respectfully request entry of the formal drawings. Applicants submit that no new matter is introduced by entry of the formal drawings.

Rejection of claims 1, 3-11 and 17 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1, 3-11 and 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting “a coding region” instead of “the coding region” because ‘a coding region’ reads on a codon.”

Applicants respectfully disagree. Applicants respectfully submit that one skilled in the art would not reasonably envision the term “a coding region” to read on a single codon. Nevertheless, in the interest of expediting prosecution and in accordance with the Examiner’s suggestion, claims 1 and 3 have been amended to recite “the coding region,” thus rendering the rejection of claims 1, 3-11 and 17 moot.

Rejection of claim 17 under 35 U.S.C. § 112, first paragraph (Enablement)

The Examiner has further rejected claim 17 under 35 U.S.C. 112, first paragraph, on the grounds that the specification, while being enabling for increasing the regeneration ability of a plant when compared to an untransformed plant, allegedly does not reasonably provide enablement for altering the regeneration ability of a plant.

While Applicants maintain that claim 17 as previously pending is fully enabled in view of the teachings of the specification and the knowledge in the art, claim 17 has been amended to be directed to “[a]n agent for increasing the regeneration ability of a plant,” in accordance with the Examiner’s recommendation, thereby rendering the foregoing rejection moot. Indeed, Applicants submit that the specification fully enables one of ordinary skill in the art to increase the regeneration ability of a plant utilizing the claimed compositions without undue experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 17 as failing to comply with the enablement requirement.

Rejection of claims 1, 4, 6-11 and 17 under 35 U.S.C. § 103(a)

Claims 1, 4, 6-11 and 17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Terada *et al.* (*Biosci. Biotechnol. Biochem.*, Vol. 59, pp. 2183-2185, 1995) (hereinafter “Terada”).

Applicants respectfully traverse this rejection. As an initial matter, Applicants submit that the claimed invention exhibits surprising and unexpected activity as compared to the prior art, in particular, to Terada. Specifically, the Kasalath NiR protein (*i.e.*, SEQ ID NO:3) of the present invention exhibits unexpected and significantly higher activity than the protein of

Terada, as noted and confirmed by way of experimental evidence in the specification. Example 4 of the instant specification clearly states:

Furthermore, in a comparison of NiR enzyme activity per unit protein using the naphthyl ethylenediamine method and an NiR recombinant protein whose expression is induced by E. coli, the Kasalath NiR protein showed enzyme activity approximately 1.6 times higher than that of Koshihikari (Fig. 7). The above-mentioned results showed that the difference in regeneration ability between Koshihikari and Kasalath is primarily due to the difference in the level of transcriptional regulation of the NiR gene, and secondly due to differences in activity per molecule of the synthesized protein.

Importantly, Applicants note that the Koshihikari protein referenced above is the same protein as disclosed in Terada and cited by the Examiner.

Thus, Applicants respectfully disagree with the Examiner's allegation that *"the expression of the protein of Terrada would result in increased regeneration ability in the transformed plant host. Thus, one skilled in the art would have been motivated to express SEQ ID NO:3 with its conservative amino acid substitutions in a plant host to obtain ferredoxin nitrite reductase without any surprising or unexpected results."*

Indeed, while the protein of the present invention differs from that of Terada by a mere two conservative substitutions as asserted by the Examiner, these substitutions result in a **dramatic and unexpected 60% difference in activity.**

Such showing of unexpected results is sufficient to establish nonobviousness, even where structural similarity exists between two compositions. Applicants direct the Examiner's attention to MPEP § 2144.09 (VII) which states

A prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (Affidavit evidence which showed that claimed triethylated compounds possessed anti-inflammatory activity whereas prior art trimethylated compounds did not was sufficient to overcome obviousness rejection based on the homologous relationship between the prior art and claimed compounds.); In re Wiechert, 370 F.2d 927, 152 USPQ 247 (CCPA 1967) (a 7-fold improvement of activity over the prior art held sufficient to rebut prima facie obviousness based on close structural similarity).

In conclusion, in accordance with the foregoing standard for nonobviousness, the claimed invention exhibits significant and unexpected activity over the proteins described in the prior art, thereby rendering the presently claimed invention nonobvious over the cited art.

Furthermore, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness as set forth by MPEP § 2141(I) and in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) (hereinafter “KSR”).

The test for *prima facie* obviousness is consistent with the legal principles enunciated in *KSR. Takeda Chem. Indus., Ltd. v. Alpharma Pty., Ltd.*, 2007 U.S. App. LEXIS 15349, at *13 (Fed. Cir. 2007). “While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination. *Id.* at *13-14 (quoting KSR, 127 S. Ct. at 1731). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. KSR, 127 S. Ct. at 1731. Furthermore, the prior art reference (or references when combined) must teach or suggest all of the claim limitations (M.P.E.P. § 2143).

Applicants submit that the Office Action fails to identify a reason that would have prompted a person of ordinary skill in the art to modify the Koshihikari sequence to arrive at the sequence of the present invention. Indeed, the Office Action fails to provide any reason to alter the prior art sequence, to alter exactly two residues, and to alter these two particular residues (*i.e.*, amino acid residues 375 and 453). Certainly, there would have been no expectation that such modification would result in a 60% increase in activity of the protein.

For each of the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 4, 6-11 and 17 as being obvious over Terada *et al.*

SUMMARY

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the present filing to Deposit Account No. 12-0080 under Order No. SHO-028US, from which the undersigned is authorized to withdraw.

If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

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Respectfully submitted,

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